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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,189	10/28/2003	David A. Judd	0942.4180003	2747

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/694,189

Applicant(s)

JUDD ET AL.

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 73-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 73-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 20, 2005 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. Claims 1, 73-78 and 80-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,712,163 to Parenteau et al. combined with U.S. Patents 5,643,561 and 5,691,203 to Katsuen et al., and Imagawa et al.

The claims recite a serum-free cell culture medium capable of supporting the cultivation of epithelial cells in vitro that contains heparin, a fibroblast growth factor, and either forskolin, isoproterenol or theophylline. Further claims recite the formulations as 1X and other ingredients such as ascorbic acid, amino acids, vitamins, salts and other culture media ingredients.

U.S. Patent 5,712,163 to Parenteau et al. teaches a serum-free medium (see col. 7, line 1) is disclosed for culture of epithelial cells (see the title) that comprises a fibroblast growth factor (see col. 8, lines 35-40 thus also meeting limitations of claims 75-76) and a cAMP elevating agent defined as forskolin, isoproterenol or theophylline

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(see col. 8, lines 65-67 and col. 9, lines 1-2). The medium may include ascorbic acid and may be a 1X medium (see col. 12, line 28 and col. 13, line 19 for Medium 199 and see col. 15, line 43 for NCTC Medium 109 and 135). Other ingredients as recited in claims 80-84 are recited in the list of ingredients of each culture medium listed. The culture media that are appropriate for use in the disclosed invention of Parenteau et al. include DMEM, MEM, RPMI 1640, Medium 199, Ham's F-10, Ham's F-12, NCTC 109 and 135, and modified DMEM. The cells that are preferred to be cultured in this medium are human normal epithelial cells, particularly keratinocytes, disclosed at col. 5, lines 58-60. Claims 88-89 recite an intended use of the claimed culture medium. Under the principles of inherency, if a prior art composition, in its normal and usual operation, would necessarily perform the use claimed, then the use claimed will be considered to be anticipated by the prior art composition. When the prior art composition is the same as a composition described in the claims for carrying out the claimed use, it can be assumed the composition will inherently perform the claimed use. Further, recitations of intended use of an old composition will fail to impart patentability to an old composition. The only limitations not expressly and explicitly met by the disclosure of U.S. Patent 5,712,163 to Parenteau et al. is the inclusion of heparin in the cell culture medium and formulation of the media as a 10X medium.

U.S. Patent 5,643,561 to Katsuen et al. teaches methods of culturing adhesive cells in serum-free culture media. At col. 5, lines 58-65, adhesive cells appropriately cultured in the disclosed method are keratinocytes, vascular endothelial cells, mammary epithelial cells, corneal epithelial cells as well as tumor cells and cell lines. At col., 6,

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the patent teaches that medium is selected conveniently from media with practically the same composition as those used previously for culturing animal adhesive cells except excluding serum. Such media compositions are disclosed throughout the patent as DMEM, RCGM, and K-GM. U.S. Patent 5,643,561 to Katsuen et al. does not define all of the components of the serum-free media taught for the culture of the adhesive cells.

U.S. Patent 5,691,203 to Katsuen et al. teaches similarly methods of culturing adhesive cells in serum-free conditions. At col. 4, lines 45-50, the patent teaches that a conventional basal medium is appropriate as a starting material, and from lines 50-60, such basal media are identified as BME, DMEM, MEM alpha, Eagle MEM, m199, F-10, F-12 and RPMI1641. However, the patent teaches that the basal media must be supplemented with proteins and growth factors as appropriate. At col. 6, lines 28-60, the patent teaches the growth factors and hormones that may be used either singly or in a mixture. Epithelial growth factor, acidic fibroblast growth factor, basic fibroblast growth factor, hydrocortisone, insulin and heparin are explicitly disclosed as appropriate to be added to the serum-free culture media for adhesive cells.

Finally, Imagawa et al. teach that serum-free culture of mammary epithelial cells required the addition of heparin to the culture media to produce multifold growth stimulation when acidic FGF was included in the culture medium.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the culture media as claimed containing heparin, a fibroblast growth factor and either forskolin, isoproterenol or theophylline and other ingredients as further claimed. One of ordinary skill in the art would have been

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motivated to include these ingredients because each ingredient is taught to provide a beneficial effect in serum-free culture of epithelial cell lines. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) (Claimed agricultural bagging machine, which differed from a prior art machine only in that the brake means were hydraulically operated rather than mechanically operated, was held to be obvious over the prior art machine in view of references which disclosed hydraulic brakes for performing the same function, albeit in a different environment.). There would have been a reasonable expectation of success due to the multiple variations of serum-free culture media taught by the various prior art references, all of which teach successful serum-free culture of epithelial cells with use of the variations.

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,712,163 to Parenteau et al. combined with U.S. Patents 5,643,561 and 5,691,203 to Katsuen et al., and Imagawa et al. and further in view of WO9222637.

The limitations of claim 79 recite a 10X concentrated medium formulation.

WO9222637 teaches that medium concentrations of 10X are conventional and well within the skill of the practitioner. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the culture media

suggested by the primary references (as discussed above) as a 10X concentration with the expected benefits attendant thereto.

### ***Double Patenting***

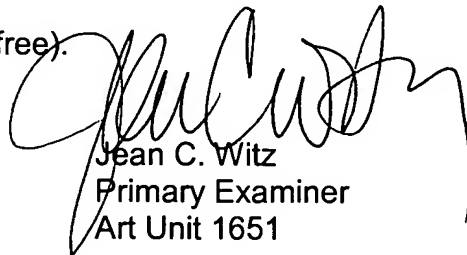
3. Claims 1 and 73-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. U.S. 6,692,961. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite an specific embodiment of the generic claims of the instant application and therefore anticipate the instant claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz  
Primary Examiner  
Art Unit 1651